

STANDARD OPERATING PROCEDURE (SOP)

October 2015

SUBJECT: MANAGEMENT OF AND TREATMENT GUIDELINES FOR INMATES WITH HEPATITIS C

PURPOSE: To provide guidance for the treatment of Chronic Hepatitis C (HCV) infection in the RIDOC inmate population.

POLICY:

The RIDOC shall create a special board of consultant Infectious Disease experts and employed RIDOC providers who shall evaluate all requests for treatment of Hepatitis C infection in inmates and to monitor patients along with their Primary Care Provider, who have Hepatitis C.

Hepatitis C assessment and treatment management is complex and shall be under the direct supervision of the Primary Care Provider with guidance from an infectious disease specialist consultant or Hepatologist contracted by the RIDOC with experience in the management of this disease.

Evaluation of candidates for treatment of Hepatitis C, as well as implementation of therapy, shall be overseen by the ID specialists, and on-site Primary Care Providers that currently manage care within RIDOC facilities. Specialists will conduct Hepatitis C clinics to meet with individuals, conduct a physical assessment and review inmate history and complete a comprehensive evaluation of the inmate's hepatic status.

The Hepatitis C (HCV) Committee shall review all requests for treatment, review cases seen in clinic, prioritize cases, and review new and emerging therapies. This review board shall be chaired by the Medical Programs Director, and shall consist of board-certified or eligible specialists in infectious diseases, or Hepatology that are familiar with management of hepatitis C; Medical providers with correctional health care concerns and practices; and the Clinical Director of Behavioral Health.

In general, the committee will follow the recommendations of the Center for Disease Control (CDC), Federal Bureau of Prisons (BOP), and the National Institute of Health (NIH), Infectious Diseases Society of America (IDSA), American Association for the Study of Liver Diseases (AASLD) regarding Hepatitis C management and treatment guideline currently in force at the time of the inmate review.

Although they will not directly recommend specific anti-viral drugs for Hepatitis C, the Primary Care Providers (PCPs) will follow the recommendations of the HCV committee for the ordering of specified treatment and provide appropriate supportive care to inmates with Hepatitis C, including management of their liver disease and its complications.

For the purposes of the SOP, there are two categories of inmates Sentenced and Awaiting Trial

PROCEDURES:

The HCV committee has established the following treatment priorities for inmates who have a more urgent need for intervention.

- 1) Inmate must have Hepatitis C virus with a detectable viral load.
- 2) A minimum of stage 3 liver fibrosis/cirrhosis should be used for prioritizing treatment consideration.
(Irreversible damage occurs when higher than stage 3.)
Abdominal imaging studies such as Fibroscan or Elastography or results from a previous liver biopsy may identify findings consistent with cirrhosis.
- 3) APRI of 2.0 or above $[(AST/40) / PLT = APRI]$
- 4) HIV co-infection
- 5) Comorbid medical conditions associated with HCV e.g. cryoglobulinemia and certain types of lymphomas
- 6) Liver transplant recipients

All those with an APRI score of equal to or greater than 1.0, or whose APRI score is between 0.7 and 1.0 with other findings suggestive of advanced fibrosis (low albumin or platelets, elevated bilirubin on INR) will be evaluated, prioritized and determined how frequently they will be monitored.

In addition, inmates being considered for treatment of HCV should have sufficient time remaining on their sentence in the RIDOC to complete the course of treatment suggested and should be willing and able to adhere to the treatment regimen and subsequent testing. Inmates held at RIDOC that are from an Out of State jurisdiction, the inmate will be sent back to the sentencing state and they will determine if the inmate will be treated. [Any female inmate who is pregnant will not be considered for treatment.]

Individuals awaiting trial will not be started on HCV treatment; however continuity of care for new commitments who were actively receiving treatment at the time of incarceration will be continued on such therapy. (If circumstances permit they will be allowed to continue regimen from the community and will be allowed to utilize such medications.)

Individuals that do not have sufficient time left in their sentence or those Awaiting Trial will be educated on community resources available. e.g. TMH Infectious Disease Clinic or Community Clinics who are treating HCV patients. Discharge planners will be involved to point inmates being released to providers in community.

Monitoring: An HCV Flowsheet will be initiated on anyone who is known HCV+

Lab orders necessary to be ordered by the PCP prior to evaluation by the committee: GT, Viral Load, CBC, LFT panel and AFP. Further liver imaging is necessary for those whose AFP or other such labs indicate risk for cancer.

Pregnancy testing will occur for any Female being considered for treatment.

HCV Viral loads need to be drawn prior to treatment.

For sofosbuvir regimens, HCV viral loads need to be drawn 4 weeks into treatment, and 12 weeks after treatment completion.

For simeprevir containing regimens, viral loads also need to be drawn after treatment weeks 4, 12, and 24 to assess response to treatment.

Recommended treatment regimens depend on the individuals' genotype and prior HCV treatment history.

Inmate patients must consent to treatment and will sign an Acknowledgment of Consent form that will be filed in the EMR

Medication doses and regimens may differ from those in compensated liver disease or chronic kidney disease. Such cases are managed in consultation with an experienced clinician specialist. For those with HIV co-infection antiretroviral medication changes may be necessary for patient being considered for HCV treatment, due to potential drug interactions between sofosbuvir or simeprevir and certain antiretrovirals. Consultation with a pharmacist and an experience clinician specialist is necessary.

Clinic cases are prioritized and discussed at HCV Committee. Recommendation for treatment is decided at the HCV committee meetings and minutes are recorded. Exceptions being those who come in on treatment are continued on such prescribed therapy. (In such cases medications from the community can be continued)

A report of inmates diagnosed with HCV, is obtained every other month through a request of the Medical Records Interdepartmental Manager and is compared with current HCV tracking spreadsheet.

Parole board minutes are reviewed and cross referenced with HCV tracking spreadsheet identifying dates of discharge.

MEDICAL DIRECTOR:



DATE: 10-22-2015

RHODE ISLAND DEPARTMENT OF CORRECTIONS HEALTH SERVICES
ACKNOWLEDGEMENT OF CONSENT - HEPATITIS C (HCV) TREATMENT

Patient Name:

D.O.B. / /

Facility:

ID#:

Doctor:

I agree that:

1. I am asking for care of my Hepatitis C (HCV) infection.
2. I have had a chance to talk about my Hep C the risks, benefits, and side-effects of this care; along with the risks of no treatment at all, with a doctor.
3. The doctor suggested:

(write in name of medication, how I will take it and how many times a day :)

4. I understand that this treatment will be watched closely by doctors and nurses; I will need lab work as well.. Also, a nurse will watch to make sure I swallow my medication.
5. I understand this medication may not work on getting rid of this virus from my body; I understand that I may still have problems with Hep C or other related illnesses.
6. I understand that I cannot receive Hepatitis C medication by the RIDOC while on Probation and Parole, Home Confinement, or any other program outside of our facilities.
7. I understand that therapy will continue for several months, and that stopping and/or starting the medication may not give me the best results.
8. I will work with the doctor and nurses. This includes undergoing a liver biopsy if needed, taking my medications, showing up for my doctor visits, and having blood work and other tests when needed.
9. I understand the doctor may need to adjust my medications if side-effects occur, or may even need to stop the medication all together.
10. I understand the medication will be stopped if I refuse the tests that need to be done while taking this medication.
11. I understand that treatment will be stopped if I do not take all my medication as directed.
12. I understand that if my treatment is stopped because I refuse to take my medication or to do the needed testing, it may not be restarted.

(check one box ONLY)

☐ I agree to the treatment as described and agree to follow the instructions.

☐ I do not agree to this treatment.

Patient

Date

Education was provided verbally on _____

Date

Provided by:

Practitioner's Acknowledgement

The undersigned confirms that the patient as described above, has given informed consent.

Practitioner

Date

HCV Flowsheet

Name: _____ DOB: _____ DOR: _____ HCV Dg: _____ GT: _____ Previous TX: _____
 VL: _____

Date	HCT	WBC	PLT	ALT	PCR	GLU	BUN	CR	NA	CL	CO2	TSH	TREATMENT
													Start Date:
													End Date:
													Drug:
													Consent:

	HIV	HAV Titer	HBV Titer	TwinRx Vaccine	Fibrosis	Date	Findings	
Date:					US			Comments:
Results					MRI			
					Liver Biopsy/ Fibroscan			
Clinic Date:					Issues			
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